

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
AND THE APPLICATION REVIEW SUBCOMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: MAY 24, 2018
11 A.M.

REPORTER: BETH C. DRAIN, CSR
CA CSR. NO. 7152

FILE NO.: 2018-09

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION:	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS. (CLIN-1, 2 OR 3).	6
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO PARTNERING OPPORTUNITY: TRANSLATIONAL RESEARCH PROJECTS.	13
CLOSED SESSION:	NONE
5. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEMS "3" AND "4" ABOVE. (HEALTH & SAFETY CODE 125290.30(F)(3)(B) AND (C)).	
6. PUBLIC COMMENT.	
7. ADJOURNMENT.	28

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THURSDAY, MAY 24, 2018

11 A.M.

VICE CHAIRMAN TORRES: THANK YOU VERY MUCH, MARIA. THE MEETING OF OUR SUBCOMMITTEE, THE ICOC REVIEW APPLICATION SUBCOMMITTEE WILL COME TO ORDER. MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. DAVE MARTIN.

DR. MARTIN: PRESENT.

MS. BONNEVILLE: LAUREN MILLER. ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: PRESENT.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: HERE.

1 MS. BONNEVILLE: AL ROWLETT.
2 MR. ROWLETT: HERE.
3 MS. BONNEVILLE: JEFF SHEEHY.
4 SUPERVISOR SHEEHY: HERE.
5 MS. BONNEVILLE: OS STEWARD.
6 DR. STEWARD: HERE.
7 MS. BONNEVILLE: JONATHAN THOMAS. ART
8 TORRES.
9 MR. TORRES: HERE.
10 MS. BONNEVILLE: DIANE WINOKUR.
11 WE HAVE A QUORUM. THANK YOU, ART.
12 DR. GASSON: MARIA, THIS IS JUDY GASSON.
13 MS. BONNEVILLE: SORRY. I FORGOT TO ASK
14 IF THERE WERE OTHER BOARD MEMBERS WHOM I DID NOT
15 CALL ON THE LINE.
16 DR. MALKAS: LINDA MALKAS.
17 DR. GASSON: JUDY GASSON.
18 MS. BONNEVILLE: THANK YOU, JUDY AND
19 LINDA.
20 VICE CHAIRMAN TORRES: OKAY. JEFF, ARE
21 YOU JOINING US FOR THE WHOLE MEETING? WE HEARD THAT
22 YOU MIGHT NOT BE ABLE TO, BUT GLAD TO HAVE YOU ON.
23 SUPERVISOR SHEEHY: FOR A WHILE.
24 VICE CHAIRMAN TORRES: OKAY. WE'LL TRY TO
25 GET QUICKLY THROUGH THIS. I THINK WE'RE BOTH

1 SUFFERING THROUGH COLDS.

2 FIRST OF ALL, I WANTED TO CONGRATULATE
3 LIZZY THOMAS. OUR CHAIRMAN, JON THOMAS, IS AT
4 HARVARD AS WE SPEAK FOR HIS DAUGHTER'S GRADUATION.
5 TIME CERTAINLY FLIES, SO WE WISH HIM AND THE FAMILY
6 TREMENDOUS CONGRATULATIONS ON BEHALF OF HER GREAT
7 ACHIEVEMENT.

8 SECONDLY, AS WE'VE EVOLVED AS AN
9 ORGANIZATION AND OUR PATIENT ADVOCATE COMMUNITY HAS
10 GROWN, WE UNDERSTAND THAT IT'S SOMETIMES DIFFICULT
11 FOR SOME MEMBERS OF THE PUBLIC TO PHYSICALLY ATTEND
12 OUR PUBLIC LOCATIONS. THEREFORE, WE HAVE
13 IMPLEMENTED THE FOLLOWING PROCESS IN ORDER TO ENABLE
14 MEMBERS OF THE PUBLIC TO ASK QUESTIONS AND MAKE
15 PUBLIC COMMENT DURING OUR MEETINGS OVER THE PHONE.

16 ONCE WE HAVE CALLED FOR PUBLIC COMMENT,
17 MEMBERS OF THE PUBLIC WILL BE ABLE TO DO SO BY PRESSING
18 1, WHICH WILL PLACE YOU IN LINE TO MAKE YOUR PUBLIC
19 COMMENT. ONCE WE CALL YOUR NAME, YOU WILL HAVE
20 THREE MINUTES TO MAKE YOUR PUBLIC COMMENT. AND
21 PLEASE BEAR WITH US IF THERE ARE ANY DELAYS OR
22 TECHNICAL DIFFICULTIES. AND THIS IS THE FIRST TIME
23 WE'RE TRYING TO PROVIDE THIS PROCESS WHICH I THINK
24 WILL BRING MUCH MORE TRANSPARENCY TO OUR
25 ORGANIZATION AND PROVIDE OPPORTUNITY FOR MUCH MORE

1 INPUT FROM THE PUBLIC AND, QUITE FRANKLY, ALSO FROM
2 OUR APPLICANTS.

3 ARE THERE ANY QUESTIONS? ALL RIGHT. I
4 THINK WE'RE GOING TO TURN OVER THE MEETING NOW TO
5 OUR FIRST AREA, WHICH WILL BE SHYAM PATEL, AND HE'S
6 GOING TO PROVIDE THE INTRODUCTORY REMARKS, AND THEN
7 JEFF WILL TAKE OVER AS CHAIR.

8 DR. PATEL: THANK YOU, ART. I'M GOING TO
9 TURN IT OVER TO AMY REAL QUICK SO SHE CAN COMMENT ON
10 HOW PEOPLE CAN MAKE COMMENTS.

11 MS. CHEUNG: JUST TO CLARIFY, IF YOU ARE A
12 MEMBER OF THE PUBLIC WHO IS ON THE PHONE AT A
13 NON-NOTICED LOCATION, YOU WILL HIT STAR 1 TO MAKE
14 PUBLIC COMMENT, AND CALL THEN WE'LL UPON YOU AT THAT
15 TIME. THANK YOU.

16 DR. PATEL: SO THIS IS SHYAM PATEL, AND
17 I'M GOING TO BE PRESENTING THE CLINICAL PROGRAM GWG
18 RECOMMENDATIONS TO THE BOARD TODAY. AND I JUST WANT
19 TO NOTE THAT I HAVE DR. GIL SAMBRANO HERE FOR MORAL
20 SUPPORT.

21 SO TO GET STARTED, JUST AS A REMINDER,
22 EACH PROGRAM HAS THREE FUNDING OPPORTUNITIES, CLIN1,
23 2, AND 3. BEFORE YOU TODAY IS A SINGLE CLIN2
24 APPLICATION FOR A CLINICAL TRIAL STAGE PROJECT.

25 AND BEFORE I GET INTO THAT, I JUST WANT TO

1 GIVE YOU AN UPDATE ON THE SCORING SYSTEM. AGAIN, A
2 SCORE OF 1 INDICATES THAT IT'S OF EXCEPTIONAL MERIT
3 AND WARRANTS FUNDING; A SCORE OF 2 ON AN APPLICATION
4 INDICATES THAT THE APPLICATION NEEDS IMPROVEMENT AND
5 DOES NOT WARRANT FUNDING AT THIS TIME, BUT CAN BE
6 RESUBMITTED TO ADDRESS AREAS FOR IMPROVEMENT; AND
7 FINALLY A SCORE OF 3 WOULD INDICATE THIS APPLICATION
8 IS SUFFICIENTLY FLAWED AND DOES NOT WARRANT FUNDING,
9 AND THE SAME PROJECT SHOULD NOT BE RESUBMITTED FOR
10 AT LEAST SIX MONTHS.

11 TODAY, AS I MENTIONED, IS A CLIN2
12 APPLICATION FOR YOUR REVIEW. THIS IS CLIN2-10784,
13 WHICH IS A PHASE 1 CLINICAL TRIAL FOR A THERAPY FOR
14 SMALL -- FOR NON-SMALL CELL LUNG CANCER.

15 THE THERAPY ITSELF IS INTRATUMORAL
16 ADMINISTRATION OF AUTOLOGOUS EX VIVO OF CCL21
17 GENE-MODIFIED DENDRITIC CELLS COMBINED WITH
18 INTRAVENOUS ADMINISTRATION OF PEMBROLIZUMAB
19 ANTIBODY.

20 AND INDICATION IS FOR PATIENTS WITH STAGE
21 FOUR ADVANCED NON-SMALL CELL LUNG CANCER, AND THE
22 GOAL OF THIS PARTICULAR PROJECT IS TO COMPLETE A
23 PHASE 1 CLINICAL TRIAL TO ASSESS SAFETY, MAXIMUM
24 TOLERATED DOSE, AND OVERALL EFFECTIVE RESPONSE RATE
25 OF THE THERAPY.

1 THE FUNDS REQUESTED ARE ROUGHLY \$12
2 MILLION. THERE'S ALSO \$400,000 IN CO-FUNDING BEING
3 PUT UP BY THE APPLICANT.

4 THE GWG RECOMMENDATION FOR THIS PARTICULAR
5 APPLICATION WAS THAT IT HAS EXCEPTIONAL MERIT AND
6 WARRANTS FUNDING. THERE WERE 15 MEMBERS WHO SCORED
7 IT, AND IT WAS A UNANIMOUS VOTE FOR THIS
8 APPLICATION. THE CIRM TEAM RECOMMENDATION IS TO
9 FUND, AND WE CONCUR WITH THE GWG RECOMMENDATION FOR
10 THE FULL REQUESTED AMOUNT OF \$11,993,073. ART.

11 VICE CHAIRMAN TORRES: YES. I JUST WANTED
12 TO MAKE SURE IF JEFF WANTED TO INTERVENE HERE. I
13 KNOW JEFF IS NOT FEELING WELL.

14 MS. BONNEVILLE: ART, I THINK YOU'LL BE
15 CHAIRING THIS PORTION AS WELL.

16 VICE CHAIRMAN TORRES: I KNOW JEFF IS NOT
17 FEELING WELL THIS MORNING. HOPE HE GETS BETTER.

18 YES. IS THERE ANY DISCUSSION FROM THE
19 MEMBERS OF THE BOARD ON THIS APPLICATION AND
20 RECOMMENDATION BY THE STAFF?

21 DR. MARTIN: I HAVE MAYBE A SIMPLE
22 QUESTION. WITH THE INFORMATION THAT I SAW ON THIS,
23 I DIDN'T SEE ANYTHING ABOUT A STEM CELL. CAN YOU
24 TELL ME THE RELATIONSHIP OF THIS PROJECT TO THE
25 MISSION?

1 DR. PATEL: CERTAINLY. OUR ELIGIBILITY
2 CRITERIA FOR A CELL THERAPY PRODUCT ARE THAT IT
3 COULD BE EITHER BE COMPOSED OF STEM CELLS OR BE
4 MANUFACTURED FROM STEM CELLS. IN THIS PARTICULAR
5 INSTANCE, THE CELLS WILL BE THE DENDRITIC CELLS ARE
6 MANUFACTURED FROM MONOCYTES, WHICH MEET THE PROP 71
7 DEFINITION OF PROGENITOR CELLS.

8 DR. MARTIN: OKAY. THANKS. NEWS TO ME.
9 THANK YOU.

10 VICE CHAIRMAN TORRES: ANY OTHER QUESTIONS
11 BY MEMBERS OF THE BOARD?

12 DR. DULIEGE: THIS IS ANNE-MARIE.

13 VICE CHAIRMAN TORRES: CAN WE MOVE TO
14 PUBLIC COMMENT?

15 MS. BONNEVILLE: ANNE-MARIE HAS A
16 QUESTION, ART.

17 DR. DULIEGE: I ASSUME ARE ASKED TO MAKE
18 OUR RECOMMENDATIONS BASED ON THE SCIENTIFIC MERIT AS
19 GUIDED BY THE GWG ON THE AMOUNT OF MONEY THAT IS
20 REQUESTED AND THE COMPARATIVELY LOW AMOUNT OF
21 CO-FUNDING PROVIDED FOR THIS APPLICATION. IS THAT
22 CORRECT? IS THAT WE'RE TALKING ABOUT SCIENCE, NOT
23 MONEY AND CO-FUNDING.

24 DR. PATEL: THE APPLICANT WAS NOT REQUIRED
25 TO PROVIDE ANY CO-FUNDING, SO HERE THE FUNDING IS

1 VOLUNTARY.

2 DR. DULIEGE: OKAY. THANK YOU.

3 VICE CHAIRMAN TORRES: ANY OTHER QUESTIONS
4 FROM MEMBERS OF THE BOARD? ANY PUBLIC COMMENT AT
5 ANY OF OUR LOCATIONS? HAS ANYONE CALLED IN, AMY.

6 MS. CHEUNG: NO. THERE IS NO PUBLIC
7 COMMENT ON THE PHONE.

8 VICE CHAIRMAN TORRES: IN ORDER TO RECEIVE
9 A MOTION ON THIS RECOMMENDATION, IS THERE SUCH A
10 MOTION?

11 DR. HIGGINS: SO MOVED.

12 VICE CHAIRMAN TORRES: MOVED BY DR.
13 HIGGINS. IS THERE A SECOND?

14 DR. DULIEGE: I SECOND.

15 VICE CHAIRMAN TORRES: ANNE-MARIE SECONDS.
16 ALL RIGHT. ANY OTHER FURTHER DISCUSSION?

17 DR. JUELSGAARD: I WANT TO GO BACK
18 ACTUALLY TO DR. MARTIN'S QUESTION BECAUSE I'M
19 READING FROM A NOTE THAT MARIA MILLAN SENT ME ON THE
20 DEFINITION THAT WE USE FOR THE BREADTH OF THERAPIES
21 THAT WE SUPPORT BACK IN APRIL. AND THE ONE THAT
22 SEEMS MOST APPROPRIATE, AND THIS WHERE I'D LIKE TO
23 KNOW WHAT SPECIFIC LANGUAGE IN THIS LONG SENTENCE WE
24 RELY ON TO SAY THAT THIS IS WITHIN THE SCOPE OF WHAT
25 WE'LL FUND.

1 IT SAYS A CELL THERAPY WHERE STEM OR
2 PROGENITOR CELLS, COLLECTIVELY STEM CELLS, EITHER
3 COMPOSE THE THERAPY OR ARE USED TO MANUFACTURE THE
4 CELL THERAPY. MINIMALLY MANIPULATED BONE MARROW,
5 MINIMALLY MANIPULATED CORD BLOOD, OR UNMODIFIED
6 HEMOPOIETIC STEM CELLS ARE ELIGIBLE ONLY IF BEING
7 DEVELOPED AS A NOVEL METHOD OF ADDRESSING A RARE OR
8 UNMET NEED AND UNLIKELY TO RECEIVE FUNDING FROM
9 OTHER SOURCES.

10 SO THE NEXT ONE IS ABOUT SMALL MOLECULES,
11 AND THEN YOU TALK ABOUT DEVICES, AND THEN WE GO TO
12 DISC AND TRAN. IN THE DEFINITION THAT I READ, WHAT
13 SPECIFICALLY PART OF THAT DEFINITION DOES THIS
14 PARTICULAR THERAPY FALL INTO?

15 DR. PATEL: TO ANSWER YOUR QUESTION,
16 STEVE, THIS IS SHYAM AT CIRM. SO IT FALLS IN THE
17 DEFINITION OF A CELL THERAPY OR STEM OR PROGENITOR
18 CELLS ARE USED TO MANUFACTURE THE CELL THERAPY. SO
19 NOW THE PROGENITOR CELL DEFINITION AS DEFINED BY
20 PROP 71 IS THAT THESE -- PROGENITOR CELLS ARE
21 MULTIPOTENT OR PRECURSOR CELLS THAT ARE PARTIALLY
22 DIFFERENTIATED, BUT RETAIN THE ABILITY TO DIVIDE AND
23 GIVE RISE TO DIFFERENTIATED CELLS. IN THIS
24 PARTICULAR INSTANCE, MONOCYTES THAT WOULD BE DERIVED
25 FROM THE PERIPHERAL BLOOD CELLS WOULD MEET THAT

1 DEFINITION OF PROGENITOR CELLS BECAUSE THEY ARE
2 CAPABLE IN SOME INSTANCES OF DIVIDING. AND IN THIS
3 PARTICULAR INSTANCE, THEY GAVE RISE TO
4 DIFFERENTIATED DENDRITIC CELLS. AND WE HAVE HAD
5 OTHER PROJECTS THAT HAVE MET THIS DEFINITION BEFORE
6 AS WELL.

7 DR. JUELSGAARD: THANK YOU VERY MUCH.

8 VICE CHAIRMAN TORRES: DOES THAT ANSWER
9 YOUR QUESTION, STEVE?

10 DR. JUELSGAARD: YES, IT DOES.

11 VICE CHAIRMAN TORRES: ALL RIGHT. ANY
12 FURTHER DISCUSSION ON THIS MOTION? THERE BEING
13 NONE, MARIA, PLEASE CALL THE ROLL.

14 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

15 DR. DULIEGE: YES.

16 MS. BONNEVILLE: DAVID HIGGINS.

17 DR. HIGGINS: YES.

18 MS. BONNEVILLE: STEVE JUELSGAARD.

19 MR. JUELSGAARD: YES.

20 MS. BONNEVILLE: DAVE MARTIN.

21 DR. MARTIN: YES.

22 MS. BONNEVILLE: LAUREN MILLER. ADRIANA
23 PADILLA.

24 DR. PADILLA: YES.

25 MS. BONNEVILLE: JOE PANETTA.

1 MR. PANETTA: YES.
2 MS. BONNEVILLE: FRANCISCO PRIETO.
3 DR. PRIETO: AYE.
4 MS. BONNEVILLE: ROBERT QUINT.
5 DR. QUINT: ABSTAIN.
6 MS. BONNEVILLE: AL ROWLETT.
7 MR. ROWLETT: YES.
8 MS. BONNEVILLE: JEFF SHEEHY.
9 SUPERVISOR SHEEHY: ABSTAIN.
10 MS. BONNEVILLE: OS STEWARD.
11 DR. STEWARD: YES.
12 MS. BONNEVILLE: JONATHAN THOMAS. ART
13 TORRES.
14 MR. TORRES: AYE.
15 MS. BONNEVILLE: DIANE WINOKUR.
16 MS. BONNEVILLE: MOTION CARRIES.
17 VICE CHAIRMAN TORRES: ALL RIGHT. SHYAM,
18 YOU HAVE ANOTHER PROPOSAL OR ARE WE DONE WITH THE
19 PRESENTATION?
20 DR. PATEL: WE'RE DONE WITH THE CLIN
21 PRESENTATION, AND WE'RE MOVING ON TO THE TRAN.
22 VICE CHAIRMAN TORRES: DR. SAMBRANO, WOULD
23 YOU PROCEED PLEASE.
24 DR. SAMBRANO: THANK YOU VERY MUCH,
25 MR. TORRES. GOOD MORNING, EVERYONE.

1 SO I'M GOING TO PRESENT AN OVERVIEW ON THE
2 TRANSLATION PROGRAM JUST TO MAKE SURE THAT WE'RE ALL
3 ON THE SAME PAGE REGARDING THE PROGRAM AND WHERE IT
4 FITS IN OUR FUNDING OPPORTUNITIES.

5 SO THE TRANSLATION PROGRAM COMES BETWEEN
6 OUR EARLY DISCOVERY AND THE CLINICAL PROGRAMS. THE
7 TRANSLATION PROGRAM IS INTENDED TO SUPPORT PROMISING
8 STEM CELL-BASED PROJECTS THAT WILL ACCELERATE
9 COMPLETION OF CLINICAL TRIAL STAGE ACTIVITIES THAT
10 ARE NECESSARY TO ADVANCE THOSE PROJECTS INTO
11 CLINICAL STUDY OR, IF THEY ARE A TOOL, INTO BROAD
12 END USE. AS A RESULT, WE SUPPORT PROJECTS THAT WILL
13 PROPOSE A CANDIDATE THAT'S EITHER A THERAPEUTIC,
14 COULD BE A DIAGNOSTIC, A MEDICAL DEVICE, OR A TOOL.
15 AND WE HAVE SPECIFIC REQUIREMENTS UNDER THE TRAN1
16 THROUGH 4 PROGRAM TO DEFINE EACH OF THESE PRODUCT
17 TYPES.

18 AND IN GENERAL FOR THE DIFFERENT PRODUCT
19 TYPES, THE EXPECTATION AT THE ONSET, THAT IS, WHEN
20 AN APPLICANT BRINGS A PROPOSAL TO US, IS THAT THEY
21 HAVE IDENTIFIED A CANDIDATE, A SINGLE CANDIDATE,
22 WHERE THEY HAVE DEMONSTRATED A PROOF OF CONCEPT.
23 FOR A THERAPEUTIC, FOR EXAMPLE, THAT THEY HAVE SHOWN
24 IN AN IN-VIVO MODEL DISEASE MODIFYING ACTIVITY; OR
25 IF IT'S A MEDICAL DEVICE, THAT THEY HAVE DEVELOPED A

1 PROTOTYPE WHERE THEY HAVE SHOWN PROOF OF CONCEPT IN
2 TERMS OF ITS FUNCTION.

3 AND THEN THE OUTCOME THAT'S EXPECTED AFTER
4 24 TO 30 MONTHS OF HAVING THE TRAN AWARD IS THAT
5 THEY WILL THEN BE READY FOR A PRE-IND, THE IDE, OR
6 PRESUBMISSION MEETING AS IS APPROPRIATE FOR THE
7 PRODUCT THAT THEY ARE DEVELOPING; OR IF IT'S A TOOL,
8 TO HAVE A DESIGN THAT'S READY TO TRANSFER TO
9 MANUFACTURING.

10 THE REVIEW CRITERIA THAT THE GRANTS
11 WORKING GROUP OR GWG UTILIZE TO ASSESS THESE
12 PROJECTS ARE THE BASIC QUESTIONS THAT INCLUDE DOES
13 THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND
14 POTENTIAL FOR IMPACT? THERE, OBVIOUSLY, WE'RE
15 LOOKING FOR THE VALUE THAT IT BRINGS.

16 (SHORT PAUSE.)

17 DR. SAMBRANO: SORRY ABOUT THAT. WE WERE
18 GETTING SOME FEEDBACK. SO IF YOU CAN MUTE YOUR LINE
19 SO THAT --

20 VICE CHAIRMAN TORRES: PLEASE MUTE YOUR
21 LINE. CAN YOU GO BACK BECAUSE IT WAS NOT CLEAR TO
22 ME AS WELL THE LAST EDITS YOU HAVE.

23 DR. SAMBRANO: SURE. ON THE REVIEW
24 CRITERIA, THESE ARE THE CRITERIA THAT ARE UTILIZED
25 BY THE GRANTS WORKING GROUP IN ORDER TO ASSESS THESE

1 PROJECTS. SO THE FIRST ONE IS DOES THE PROJECT HOLD
2 THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT?
3 WE ARE LOOKING THERE FOR THE OVERALL VALUE THAT THIS
4 BRINGS TO PATIENTS AS WELL AS IN TERMS OF DEVELOPING
5 A PRODUCT THAT WILL BE MEANINGFUL TO THOSE PATIENTS.

6 IS THE RATIONALE SOUND, MEANING DO THEY
7 HAVE SUFFICIENT PRELIMINARY DATA AND A CONCEPT THAT
8 IS PRACTICAL AND MAKES SENSE.

9 IS THE PROJECT WELL PLANNED AND DESIGNED.

10 AND IS THE PROJECT FEASIBLE, MEANING DOES
11 THE PROJECT HAVE THE APPROPRIATE TEAM, THE
12 APPROPRIATE RESOURCES TO MAKE THE PROJECT HAPPEN IN
13 A TIMELY FASHION?

14 THE SCORING SYSTEM THAT WE USE IN THE TRAN
15 PROGRAM IS DIFFERENT FROM CLINICAL. SO HERE WE USE
16 THE SCALE OF 1 TO 100. AND THOSE THAT ARE
17 RECOMMENDED FOR FUNDING WOULD SCORE BETWEEN 85 AND
18 100. AND THOSE NOT RECOMMENDED BETWEEN 1 AND 84.
19 AND WE USE THE MEDIAN OF ALL THE GWG INDIVIDUAL
20 SCORES IN ORDER TO DETERMINE THE FINAL SCORE.

21 SO FOR THIS PARTICULAR CYCLE OF THE
22 TRANSLATION PROGRAM, WE HAVE FOUR APPLICATIONS OUT
23 OF 14 THAT WERE RECOMMENDED BY THE GWG. THE TOTAL
24 AMOUNT REQUESTED ACROSS THESE FOUR APPLICATIONS IS
25 ABOUT \$14 MILLION. WE HAVE AVAILABLE, BASED ON THE

1 ALLOCATION THAT WE MADE FOR THIS YEAR, 30 MILLION.
2 SO IT'S JUST UNDER HALF OF THE AMOUNT THAT WE HAVE
3 FOR TRAN FOR THIS YEAR.

4 WE ANTICIPATE THIS BEING ONE OF TWO CYCLES
5 FOR THE YEAR. SO IT PUTS US PRETTY MUCH RIGHT ON
6 TARGET IN TERMS OF THE BUDGET AMOUNT FOR THIS YEAR.

7 MR. TORRES, I CAN PRESENT AN OVERVIEW OF
8 EACH OF THE -- JUST A VERY BRIEF OVERVIEW OF THE
9 RECOMMENDED APPLICATIONS, IF YOU WISH, OR WE CAN
10 LEAVE IT AS YOU WOULD LIKE US TO DO.

11 VICE CHAIRMAN TORRES: I THINK IT'S
12 IMPORTANT FOR YOU TO REVIEW THE APPLICATIONS VERY
13 QUICKLY FOR THE MEMBERS.

14 DR. SAMBRANO: SURE, ABSOLUTELY.

15 SO THE FIRST APPLICATION, AND SO I'M GOING
16 TO DO THESE IN ORDER OF RANK. THE FIRST ONE IS
17 TRAN1-10958. AND SO THE TITLE OF THIS APPLICATION
18 IS "AUTOLOGOUS IPSC-DERIVED SMOOTH MUSCLE CELL
19 THERAPY FOR THE TREATMENT OF URINARY INCONTINENCE."
20 AND SO THE DISEASE INDICATION IS FOR STRESS URINARY
21 INCONTINENCE, WHICH MOSTLY IMPACTS WOMEN.

22 THE PRODUCT TYPE IS A CELL THERAPY, AND SO
23 THIS IS AN AUTOLOGOUS APPROACH WHERE THEY WOULD TAKE
24 CELLS FROM THE PATIENT, GENERATE IPSC LINES, AND
25 THEN FROM THOSE GENERATE PROGENITOR SMOOTH MUSCLE

1 CELLS THAT WOULD BE INJECTED INTO THE AREA FOR
2 TREATMENT.

3 THIS APPLICATION RECEIVED A SCORE OF 90
4 WITH A UNANIMOUS VOTE OF 13 MEMBERS.

5 AND NEXT APPLICATION IS TRAN2-10990. SO
6 THIS IS A DIAGNOSTIC APPLICATION, AND THE TITLE OF
7 THIS ONE IS "DEVELOPMENT OF A NONINVASIVE PRENATAL
8 TEST FOR BETA-HEMOGLOBINOPATHIES FOR EARLIER STEM
9 CELL THERAPEUTIC INTERVENTION." SO THE DISEASE
10 INDICATION IS FOR HEMOGLOBINOPATHIES --

11 THE REPORTER: I'M SORRY, DR. SAMBRANO.
12 THIS IS BETH. I'M STILL HEARING A LOT OF RUSTLING
13 OF PAPER, WHICH OBLITERATES THE RECORD. IF WE COULD
14 PLEASE HAVE EVERYONE MUTE THAT IS NOT SPEAKING, I
15 WOULD REALLY APPRECIATE IT.

16 VICE CHAIRMAN TORRES: WELL TAKEN. WELL
17 TAKEN.

18 DR. SAMBRANO: OKAY. THANK YOU.

19 SO FOR THIS APPLICATION, THIS IS A
20 DIAGNOSTIC. THE APPROACH IS TO UTILIZE A
21 NONINVASIVE NEXT GENERATION SEQUENCING OF FETAL DNA
22 USING THE MATERNAL PLASMA. AND SO THIS WOULD HAPPEN
23 MUCH EARLIER THAN CVS OR AMNIOCENTESIS.

24 THIS APPLICATION RECEIVED A SCORE OF 90
25 WITH UNANIMOUS VOTE OF 14 MEMBERS OF THE GWG.

1 THE NEXT APPLICATION IS TRAN1-10937. THE
2 TITLE IS THERAPEUTIC DEVELOPMENT OF AN OXYSTEROL
3 WITH BONE ANABOLIC AND ANTI-ABSORPTIVE PROPERTIES
4 FOR INTERVENTION IN OSTEOPOROSIS. SO THE DISEASE
5 INDICATION OBVIOUSLY IS FOR OSTEOPOROSIS. THIS IS A
6 SMALL MOLECULE COMBINATION. IT IS A DRUG CONJUGATE
7 THAT TAKES TWO SMALL MOLECULES AND BRINGS THEM
8 TOGETHER WITH THE IDEA OF HAVING BOTH BONE TARGETING
9 RESORPTIVE PROPERTIES AS WELL AS THE OSTEOGENIC
10 PROPERTIES.

11 THE SCORE FOR THIS APPLICATION WAS 85 WITH
12 11 MEMBERS GIVING IT A SCORE OF 85 OR HIGHER AND TWO
13 MEMBERS THAT SCORED IT BELOW 85.

14 AND THEN THE LAST APPLICATION IS
15 TRAN1-10995. THIS ONE IS TITLED "MORPHOLOGICAL AND
16 FUNCTIONAL INTEGRATION OF STEM CELL DERIVED RETINA
17 ORGANOID SHEETS INTO DEGENERATING RETINA MODELS."
18 THE DISEASE INDICATION FOR THIS IS RETINITIS
19 PIGMENTOSA. IT IS A CELL THERAPY AND DERIVED FROM
20 HUMAN EMBRYONIC STEM CELLS, AND THESE SHEETS WOULD
21 BE TRANSPLANTED INTO PATIENTS WITH RETINITIS
22 PIGMENTOSA IN ORDER TO PROVIDE BOTH ENGRAFTMENT AND
23 CELL REPLACEMENT AS WELL AS TROPHIC EFFECTS.

24 THE SCORE FOR THIS APPLICATION WAS 85 WITH
25 NINE MEMBERS GIVING IT A SCORE BETWEEN 85 AND 100

1 AND SIX MEMBERS SCORING IT BELOW 85.

2 THAT SUMMARIZES THE APPLICATIONS THAT ARE
3 UNDER CONSIDERATION OR RECOMMENDED.

4 VICE CHAIRMAN TORRES: AND THE FOUR
5 APPLICATIONS ARE ALL RECOMMENDED BY OUR STAFF AS
6 WELL, CORRECT?

7 DR. SAMBRANO: YES. WE DON'T HAVE ANY
8 SPECIFIC RECOMMENDATION AGAINST ANY OF THESE.

9 VICE CHAIRMAN TORRES: ALL RIGHT. ALL
10 TOTAL, THEY COME TO A TOTAL OF HOW MUCH?

11 DR. SAMBRANO: 14 MILLION.

12 VICE CHAIRMAN TORRES: AND WE HAVE HOW
13 MUCH IN OUR BUDGET?

14 DR. SAMBRANO: 30 MILLION.

15 VICE CHAIRMAN TORRES: OKAY. ANY
16 QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD? I
17 WANT TO GET A SENSE OF THE BOARD WHETHER YOU WANT TO
18 VOTE ON THESE AD SERIATIM OR VOTE FOR ALL FOUR IN
19 ONE BLOCK. I GUESS THE BEST WAY TO APPROACH IT IS
20 IS THERE A MOTION TO APPROVE ALL FOUR IN OUR BOARD
21 MEETING TODAY?

22 DR. HIGGINS: SO MOVED.

23 VICE CHAIRMAN TORRES: HIGGINS MOVES. IS
24 THERE A SECOND TO APPROVE ALL FOUR.

25 MR. ROWLETT: SECOND.

1 VICE CHAIRMAN TORRES: WAS THAT AL
2 ROWLETT.

3 MR. ROWLETT: AL ROWLETT SECONDS.

4 VICE CHAIRMAN TORRES: ALL RIGHT. MR.
5 ROWLETT IS THE SECOND. AND WE MOVE INTO DISCUSSION
6 FROM -- ANY FURTHER DISCUSSION OR QUESTIONS FROM
7 BOARD?

8 DR. PRIETO: I HAVE A QUESTION. DOES THIS
9 EN BLOC MOTION ENGENDER ANY CONFLICT ISSUES?

10 MR. TOCHER: IT DOES NOT PRECLUDE ANY
11 FURTHER MOTIONS TO FUND ANY OF THE OTHER
12 APPLICATIONS.

13 DR. PRIETO: OKAY.

14 VICE CHAIRMAN TORRES: WE'RE OKAY ON
15 CONFLICTS.

16 DR. PRIETO: THANK YOU.

17 VICE CHAIRMAN TORRES: ANY FURTHER
18 QUESTIONS AND COMMENTS FROM MEMBERS OF THE BOARD?
19 ANY PUBLIC COMMENT FROM ANY OF OUR LOCATIONS
20 THROUGHOUT THE STATE?

21 MS. BONNEVILLE: YES. WE HAVE SOME PUBLIC
22 COMMENT HERE IN OAKLAND, ART.

23 VICE CHAIRMAN TORRES: OKAY. PLEASE COME
24 FORWARD, IDENTIFY YOURSELF, AND WHO YOU REPRESENT.

25 MR. REED: THIS IS DON REED, PATIENT

1 ADVOCATE. I JUST WANTED TO UNDERLINE SOMETHING I
2 THINK IS REALLY IMPORTANT ABOUT TRAN1 PROPOSAL
3 10958, WHICH IS OF GRAVE CONCERN TO MILLIONS OF
4 WOMEN ACROSS AMERICA AND AROUND THE WORLD. I KNOW
5 IT'S GOING TO PASS AND IT'S WONDERFUL, BUT I COULD
6 NOT REST UNLESS I EXPRESSED SUPPORT.

7 WHILE URINARY INCONTINENCE DOES AFFECT
8 MEN, INCLUDING SURVIVORS OF PROSTATE CANCERS LIKE
9 MYSELF, THERE'S OVERWHELMINGLY A THREAT TO WOMEN,
10 PARTICULARLY THOSE WHO HAVE BORNE CHILDREN. IT MAY
11 AFFECT AS MANY AS 50 PERCENT OF ALL ADULT WOMEN.
12 IT'S SO WIDESPREAD A PROBLEM, THAT MORE DIAPERS ARE
13 SOLD FOR ADULT USE THAN FOR BABIES.

14 IT'S ONE OF THE TOP THREE CAUSES OF WOMEN
15 BEING INSTITUTIONALIZED. NOT ONLY IS THERE THE
16 ENDLESS NEED FOR ADULT PERSONAL CARE, CHANGES OF
17 CLOTHING AND BEDDING, ASSOCIATED EMBARRASSMENT,
18 SOCIAL ISOLATION, AND DEPRESSION, BUT ACTUAL THREAT
19 OF DEATH OR INJURY AS WELL.

20 IF AN ELDERLY WOMAN RUSHES TO THE RESTROOM
21 AT NIGHT, SHE MAY FALL AND BREAK HER PELVIS, WHICH
22 CAN BE FATAL. IT IS POSSIBLE THAT THE MUSCLES OF
23 THE URETHRAL SPHINCTER MAY BE STRENGTHENED WITH BOTH
24 SMOOTH MUSCLE AND SKELETAL MUSCLE STEM CELLS. ONE
25 KIND OF MUSCLE KEEPS THE SPHINCTER CLOSED RELIABLY

1 HOURS AT A TIME. THE OTHER PROVIDES STRENGTH TO
2 CLINCH THE BLADDER'S OPENING, ALLOWING TIME TO MAKE
3 IT TO THE RESTROOM IN TIME OF EMERGENCY.

4 I HAVE STUDIED THE PROPOSAL. I'VE KNOWN
5 THIS HIGHLY RESPECTED RESEARCHER FOR MANY YEARS.
6 THE OPERATION SEEMS SIMPLE AND LIKELY TO ADVANCE TO
7 CLINICAL TRIALS. THE CELLS ARE STILL YOUTHFUL,
8 MUSCULAR CONTROL OF THE BLADDER.

9 EVERY RESEARCH PROPOSAL IS INTENDED TO
10 SOLVE A PROBLEM TO EASE SUFFERING, BUT THIS GRANT
11 MAY DIRECTLY AFFECT THE LIVES OF MORE WOMEN THAN
12 ANYTHING ELSE THAT WE DO. I CONGRATULATE THE
13 SCIENTIST INVOLVED, APPLAUD THE REVIEWERS VISION,
14 AND WHOLEHEARTEDLY ENDORSE TRAN1 PROPOSAL OF 10958.
15 THANK YOU.

16 VICE CHAIRMAN TORRES: THANK YOU, MR.
17 REED. AS A CAREGIVER FOR MY LATE MOTHER, I'M
18 ACUTELY AWARE OF HOW IMPORTANT THIS ISSUE IS.

19 ANY OTHER COMMENTS FROM MEMBERS OF THE
20 BOARD OR PUBLIC? HAS ANYONE CALLED IN?

21 MS. CHEUNG: NO. THERE ARE NO MEMBERS OF
22 THE PUBLIC ON THE LINE.

23 VICE CHAIRMAN TORRES: ALL RIGHT. I THINK
24 READY TO PROCEED TO A VOTE. PLEASE CALL THE ROLL,
25 MARIA.

1 MS. BONNEVILLE: ANNE-MARIE DULIEGE.
2 DR. DULIEGE: YES.
3 MS. BONNEVILLE: DAVID HIGGINS.
4 DR. HIGGINS: YES.
5 MS. BONNEVILLE: STEVE JUELSGAARD.
6 MR. JUELSGAARD: YES.
7 MS. BONNEVILLE: DAVE MARTIN.
8 DR. MARTIN: YES.
9 MS. BONNEVILLE: ADRIANA PADILLA.
10 DR. PADILLA: YES.
11 MS. BONNEVILLE: JOE PANETTA.
12 MR. PANETTA: YES.
13 MS. BONNEVILLE: FRANCISCO PRIETO.
14 DR. PRIETO: AYE.
15 MS. BONNEVILLE: ROBERT QUINT.
16 DR. QUINT: YES.
17 MS. BONNEVILLE: AL ROWLETT.
18 MR. ROWLETT: YES.
19 MS. BONNEVILLE: JEFF SHEEHY.
20 SUPERVISOR SHEEHY: YES.
21 MS. BONNEVILLE: OS STEWARD.
22 DR. STEWARD: YES, EXCEPT FOR THOSE WITH
23 WHICH I'M IN CONFLICT.
24 MS. BONNEVILLE: THANK YOU. ART TORRES.
25 MR. TORRES: AYE.

1 MS. BONNEVILLE: MOTION CARRIES.

2 VICE CHAIRMAN TORRES: I THINK THAT
3 CONCLUDES, CORRECT, OUR BUSINESS FOR THE DAY?

4 MS. BONNEVILLE: NOT YET, ART.

5 MR. TOCHER: SENATOR TORRES, WE STILL HAVE
6 THE REMAINING THE APPLICATIONS IS TIER II.
7 TYPICALLY WE WOULD ENTERTAIN ANY DISCUSSION OR
8 MOTION TO FUND ANY SUCH APPLICATIONS. IF THERE ARE
9 NO MOTIONS, THEN WE WOULD ENTERTAIN A MOTION TO NOT
10 FUND THE REMAINING APPLICATIONS.

11 VICE CHAIRMAN TORRES: IS THERE SUCH A
12 MOTION? THANK YOU. IS THERE A MOTION NOT TO FUND
13 THE REMAINING APPLICATIONS.

14 DR. PRIETO: I'LL SO MOVE.

15 VICE CHAIRMAN TORRES: IS THERE A SECOND?

16 DR. JUELSGAARD: SECOND.

17 VICE CHAIRMAN TORRES: STEVE JUELSGAARD IS
18 THE SECOND. ANY DISCUSSION BY MEMBERS OF THE BOARD?
19 ANY PUBLIC COMMENT AT ANY OF OUR LOCATIONS?

20 MS. BONNEVILLE: YES, WE HAVE PUBLIC
21 COMMENT HERE IN OAKLAND.

22 VICE CHAIRMAN TORRES: ALL RIGHT.

23 MR. REED: IN MY YOUTH I KNEW THE MAN WHO
24 WAS ONCE THE STRONGEST MAN IN THE WORLD IN OLYMPIC
25 WEIGHT LIFTING. AND HIS LIFE ENDED IN GREAT PAIN

1 WITH ISCHEMIC -- THE BLOOD HARDENING OF THE
2 ARTERIES. THIS IS 1032, RESTORE OF BLOOD FLOW TO
3 CLINICAL LIMB ISCHEMIA.

4 I KNOW THE AGONY THAT HE HAD. JUST HAVING
5 SEEN THAT FROM A PERSONAL VIEWPOINT, I WONDER -- I
6 DON'T KNOW ANYTHING ABOUT IT, I DIDN'T STUDY IT, BUT
7 THAT PARTICULAR AGONY, IT WOULD BE SO GREAT IF WE
8 COULD DO ANYTHING TO EASE THAT PAIN. THAT'S MY
9 THOUGHTS.

10 VICE CHAIRMAN TORRES: THANK YOU VERY
11 MUCH, MR. REED. ANY FURTHER PUBLIC COMMENT OR
12 MEMBERS OF THE BOARD? I THINK WE'RE READY TO
13 PROCEED FOR A MOTION. MARIA, PLEASE CALL THE ROLL.

14 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

15 DR. DULIEGE: AYE.

16 MS. BONNEVILLE: DAVID HIGGINS.

17 DR. HIGGINS: YES.

18 MS. BONNEVILLE: STEVE JUELSGAARD.

19 MR. JUELSGAARD: YES.

20 MS. BONNEVILLE: DAVE MARTIN.

21 DR. MARTIN: YES.

22 MS. BONNEVILLE: ADRIANA PADILLA.

23 DR. PADILLA: YES.

24 MS. BONNEVILLE: JOE PANETTA.

25 MR. PANETTA: YES.

1 MS. BONNEVILLE: FRANCISCO PRIETO.

2 DR. PRIETO: AYE.

3 MS. BONNEVILLE: ROBERT QUINT.

4 DR. QUINT: YES.

5 MS. BONNEVILLE: AL ROWLETT.

6 MR. ROWLETT: YES.

7 MS. BONNEVILLE: JEFF SHEEHY.

8 SUPERVISOR SHEEHY: YES.

9 MS. BONNEVILLE: OS STEWARD.

10 DR. STEWARD: YES, EXCEPT FOR THOSE WITH
11 WHICH I'M IN CONFLICT.

12 MS. BONNEVILLE: ART TORRES.

13 MR. TORRES: AYE.

14 MS. BONNEVILLE: MOTION CARRIES.

15 VICE CHAIRMAN TORRES: ALL RIGHT. I THINK
16 THAT DOES CONCLUDE OUR BUSINESS FOR THE DAY; IS THAT
17 CORRECT?

18 MS. BONNEVILLE: SURE DOES.

19 VICE CHAIRMAN TORRES: FIRST OF ALL, I
20 WANT TO THANK MR. SHEEHY FOR STAYING ON THE LINE AND
21 JOIN MANY OTHERS IN WISHING YOU TO A FRUITFUL
22 REELECTION AS OUR SUPERVISOR FOR SAN FRANCISCO. WE
23 ALL STAND WITH YOU AND BEST WISHES.

24 SECONDLY, WE WANT TO ADVISE MEMBERS THAT
25 WE WILL HAVE AN IN-PERSON BOARD MEETING JUNE 28TH AT

1 OUR OAKLAND OFFICES. THAT'S AN IN-PERSON BOARD
2 MEETING JUNE 28TH IN OUR OAKLAND OFFICES. AND WE
3 HOPE TO SEE YOU ALL THEN. AGAIN, MY THANKS TO ALL
4 THE STAFF WHO PARTICIPATED TODAY AND ALSO BEHIND THE
5 SCENES IN PROVIDING ADEQUATE RESEARCH FOR ALL OF OUR
6 APPLICATIONS. AND PLEASE HAVE A WONDERFUL MEMORIAL
7 DAY WEEKEND. THANK YOU.

8 MS. BONNEVILLE: THANK YOU, EVERYONE.

9 (THE MEETING WAS THEN CONCLUDED AT
10 11:34 AM.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MAY 24, 2018, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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